UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

MDL No. 01-1396 (JRT/FLN)

IN RE: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

MEMORDANDUM OPINION AND ORDER DENYING MOTIONS TO EXCLUDE TESTIMONY OF EXPERTS

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Defendant St. Jude Medical produced the Silzone prosthetic heart valve. A test conducted by defendant showed a higher risk of paravalvular leaks at the site where the valves were implanted, and defendant voluntarily recalled all Silzone valves that had not yet been implanted. Numerous lawsuits were filed across the nation, and the cases were ultimately consolidated for pretrial matters in the District of Minnesota. Defendant has

now moved to preclude testimony of three of plaintiffs' experts. For the reasons discussed below, the Court denies defendant's motions.

BACKGROUND

Defendant St. Jude has manufactured a variety of medical devices including the "Silzone" heart valve. The Silzone valve has a coating of silver on the sewing cuff, the part of the valve that is sewn to the patient's body. Silver was added to the valve because of its potential anti-microbial properties, which was hoped would combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a possible consequence of prosthetic heart valve implantation.

The Silzone valve was approved for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis. After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multi-national clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. The study enrolled 792 patients; approximately half of whom received Silzone-coated valves and another half, the control group, received conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more likely to experience a complication called paravalvular leak, requiring the prosthetic valve to be removed and replaced with another valve, compared

to recipients of conventional valves. On January 21, 2000, the monitoring board suspended enrollment in the AVERT trial because of this increase in paravalvular leak. On the same day, St. Jude voluntarily recalled all un-implanted Silzone products. As part of the recall, St. Jude immediately notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis, and treatment of paravalvular leak.

ANALYSIS

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Fed. R. Evidence 702. Under Rule 702, proposed expert testimony must satisfy three prerequisites to be admitted. *See Lauzon v. Senco Prods. Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). First, evidence based on scientific, technical, or specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. *Id.* Second, the proposed witness must be qualified. *Id.* Third, the proposed evidence must be reliable or trustworthy in the evidentiary sense, so that if the finder of fact accepts it as true, it provides the assistance the finder of fact requires. *Id.* The district court has a "gatekeeping" obligation to make certain that all testimony admitted under Rule 702 satisfies these prerequisites. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597-98 (1993). But an expert's opinion should be excluded as unreliable only if that "opinion

is so fundamentally unsupported that it can offer no assistance to the jury." *Bonner v. ISP Techs.*, 259 F.3d 924, 929 (8th Cir. 2001).

Defendant moves to preclude testimony of three of plaintiffs' experts, namely Gregory J. Wilson, Kevin E. Healy, and Eric G. Butchart. Defendant objects to certain testimony of the three experts that either concerns relief that the Court may permit plaintiffs to receive or that will not be a part of the generic expert presentation in the individual injury cases. The Court will not address those issues at this time. The Court addresses below the admissibility of the remaining testimony from each of these experts.

I. GREGORY J. WILSON

Wilson is an anatomic pathologist, who is a professor at the University of Toronto. He has published approximately 160 scientific articles, including several in the field of biomaterials relating to cardiac products. His stated research interests include "Cardiovascular prosthetic devices, especially the development and experimental evaluation of design improvements including cardiac pacing systems, heart valve prostheses and synthetic and biological vascular grafts." (Rudd Decl. Ex. 7.)

Defendant first argues that Wilson is not generally qualified to offer opinions on Silzone valves because his work experience has been limited to children. Given Wilson's credentials and his career emphasis on the cardiovascular system and on heart valves specifically, the Court finds that Wilson is qualified to generally opine on Silzone valves. The Court examines the factual basis for Wilson's specific opinions below.

A. Testimony That The Silzone Coating Is Mechanically Unstable

Wilson opines that silver comes off the Silzone coated cuff after being implanted. Defendant first argues that Wilson is not qualified to offer this specific opinion because his research experience has not involved the study of silver-coated medical devices, even though he has significant experience in material science as it relates to implantable medical devices. Despite Wilson's lack of research experience in silver-coated medical devices, the Court finds that Wilson is qualified to opine on the stability of the silver-coated valves. Wilson has observed silver flaking off the cuff of silver-coated valves and has conducted laboratory tests to confirm that the black particles he observed were silver.

B. Testimony That Silzone Patients Experience Frustrated Tissue Healing Caused By The Silzone Coating

Wilson opines that the silver that flakes off the valves plays a significant role in the frustration of the healing process. Wilson relies on the literature on silver-coated valves, defendant's studies, Wilson's observations of pathology reports and valve photographs, and the work of other experts in the field. Defendant argues that Wilson's conclusion is not sufficiently supported by facts. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Specifically, Wilson did not conduct any controlled studies and relied in large part on case reports. Further, the literature upon which Wilson relied was based on non-randomized studies. Although defendant has identified areas of weakness in Wilson's broad conclusion concerning the frustration of healing, the Court does not find that his testimony on this subject would be of "no

assistance to the jury." *Bonner*, 259 F.3d at 929-30. Wilson employed techniques and procedures that are routinely employed in the field of pathology and medical device design.

C. Testimony That Silver Is Toxic To Human Cells

Wilson also opines on the toxicity of silver. Defendant argues that Wilson has relied entirely on the research and findings of others and does not have any particular expertise in toxicology. Plaintiffs respond that Wilson is a recognized biomaterials expert and that as a practicing pathologist he deals frequently with toxicity issues. The Court has some concern that Wilson does not have personal expertise in toxicology and has not conducted any of his own research on the toxicity of silver. However, expert testimony should not be easily excluded given the "liberal thrust" of the Federal Rules of Evidence. *Daubert*, 509 U.S. at 588. The Court therefore will not exclude this opinion at this time. If a case goes to trial, and this Court presides over the trial, there may be some need to readdress the admissibility of this particular testimony.

D. Testimony That The Silzone Coating Is A Defective Product

Finally, Wilson opines that the Silzone coating is a defective product. Wilson relies on his prior affidavits, published articles from the AVERT study and Butchart, and his examination of specimens. While plaintiffs emphasize Wilson's experience in and knowledge of cardiovascular prosthetic devices, defendant argues that Wilson is not qualified to opine about the existence of a defect because he is a pathologist that deals with children. The Court finds that Wilson's opinion that the Silzone coating is defective

is a logical extension of his other opinions on the coating. The Court therefore sees no basis to exclude this testimony.

Accordingly, the Court denies defendant's motion to preclude testimony of Wilson.

II. KEVIN E. HEALY

Healy is a professor in the Department of Bioengineering and the Department of Material Science and Engineering at the University of California – Berkeley. He has expertise in the interaction of ionizing metals on permanently implanted medical devices with human blood and tissue, and he holds patents relating to stents and stent coatings.

Defendant begins by arguing that Healy is generally not qualified to offer opinions on the effects of leaching from Silzone valves because he has not worked on mechanical heart values or any silver-coated devices. Defendant's attempt to narrowly define Healy's expertise is unpersuasive. Healy has expertise in material design of medical devices, which is sufficient to make him qualified to generally opine on the effects of leaching from Silzone valves.

Healy opines on the existence of local tissue damage in Silzone patients and the risk of future medical complications, the corrosion rate of the Silzone coating, and the suitability of the Silzone coating for cardiac implantation. The Court addresses below the factual basis for these three opinions.

A. Testimony that Silzone Patients Suffered Tissue Damage and are at a Higher Risk for Future Medical Complications

Healy opines that all Silzone patients suffered local tissue damage. Defendant argues that this conclusion is based on a series of unsupported assumptions, and is therefore unreliable. For example, Healy opines that silver leaches off the Silzone valve in a concentration gradient surrounding the device and that the amount of silver entering the tissue can cause cell damage. Defendant faults Healy because the existence of the concentration gradient is an untested hypothesis. While courts allow experts to testify about hypotheses, hypotheses that are based on mere speculation and lack factual support are unhelpful to a jury and should be excluded. *See Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (excluding expert testimony that a drug causes a stroke because the underlying assumption that the drug acts as a vasoconstrictor was unsupported). The Court cannot at this time conclude that Healy's opinion on this matter is so unsupported that it would be completely unhelpful to the jury. *See Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir. 1998) (explaining that "doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility"). Nevertheless, the Court has some reservations given that there appears to be minimal factual support for Healy's hypothesis on the concentration gradient. As with Wilson's testimony on the toxicity of silver, the Court may need to readdress the admissibility of this testimony at trial.

Beyond critiquing the specific assumptions underlying Healy's opinion that the Silzone coating causes local tissue damage, defendant more broadly argues that Healy

should not be allowed to testify that Silzone results in any adverse medical event because Healy is not a medical expert and his opinion lacks factual support. The Court concludes that Healy has helpful testimony in this regard because he has knowledge and experience in interactions between metals and human tissues. He bases his opinion on relevant scientific literature, animal studies, and the histology of human explants. Defendant's objections to the factual support for Healy's opinion more appropriately go to the weight of the opinion than the admissibility. *See Bonner*, 259 F.3d at 929.

B. Testimony that SJM Should Have Been Concerned by the Alarming Corrosion Rate of the Silzone Coating

Healy opines that the Silzone coating was not inert and had poor corrosion resistance. Defendant faults Healy for basing this opinion on defendant's lab notebook entries and experimental results without having a full understanding of them. However, Healy's opinion was not solely based on these lab notebook entries and experimental results. A biomaterial expert is well suited to opine on the corrosion of the Silzone coating, and the Court will not exclude the testimony.

C. Testimony that the Silzone Coating Was Not a Proper or Suitable Biomaterial for Human Cardiac Implantation, and that Silzone Coated Prosthetic Heart Valve Products Were Defective

Healy opines that the Silzone coating was not suitable for human cardiac implantation, and that the Silzone-coated valves were defective. As with Wilson's opinion that the Silzone coating was defective, this opinion of Healy is a logical extension of Healy's other opinions on the Silzone coating. Again, defendant argues that

this testimony must be excluded because Healy lacks medical expertise. Healy offers a biomaterials opinion that is precisely within Healy's area of expertise. As long as the testimony is focused on the interaction between the metal and tissue and blood, rather than broader medical implications, the Court sees no basis for excluding it.

The Court therefore denies defendant's motion to preclude testimony of Healy.

III. ERIC BUTCHART

Butchart is a medical doctor trained as a cardiothoracic surgeon. His main interest is heart valve surgery, with an emphasis on thromboembolism after heart valve replacement. He has personally implanted 16-25 Silzone valves, and explanted three. Butchart has previously served defendant as a consultant and clinical researcher on matters relating to the design, safety, and clinical use of its prosthetic heart valves. As discussed below, defendant objects to his testimony on the basis of his qualifications and the factual support for his opinions.

A. Testimony that Silzone has Toxic Effect on Tissues and Blood Components, Causing a Higher Incidence of Medical Complications

Butchart opines that Silzone has a direct, toxic effect on tissues and blood components, which leads to a higher incidence of complications. He hypothesizes two mechanisms by which Silzone may cause damage to blood and tissues. First, Silzone may be toxic to blood platelets and therefore interfere with platelet adhesion. Second, Silzone may be toxic to red blood cells and therefore deplete intracellular glutathione.

Defendant argues that to offer an opinion on the toxicity of Silzone, an expert should have expertise in toxicology, pathology, hematology, biomaterials science, or metallurgy. Knowledge in the areas listed by defendant would buttress the credibility of Butchart's testimony, but the lack of expertise in these areas does not make Butchart unqualified. Butchart is an expert in thromboembolism after heart valve replacement, and he has knowledge in these additional areas that comes from reading the literature, talking to other experts, and attending medical conferences. The Court concludes that he is qualified to offer this opinion.

Defendant also criticizes Butchart's opinion as being unsupported by facts. Butchart has not done laboratory testing of his hypotheses. Rather, Butchart primarily relies on the literature and his observations from two explanted Silzone valves. Defendant persuasively attacks several of the sources that underlie Butchart's opinion, but defendant fails to consider the additional evidence that supports Butchart's opinions. Moreover, "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." *See Bonner*, 259 F.3d at 929. Nevertheless, as with the other experts' opinions on how the Silzone coating affects adjacent tissues, there may be some need to readdress the admissibility of this particular testimony if the case goes to trial.

B. Testimony that Silzone Causes a Higher Incidence of Wide-Ranging Complications, Thereby Rendering the Silzone Valve Defective

Butchart opines that substantial differences exist in the complication rates between the Silzone valve and defendant's standard valve. Specifically, he opines that the Silzone valve is qualitatively and quantitatively different from other heart valves in complications, including thrombosis, thromboembolism, tissue overgrowth, paravalvular leak, endocarditis, and possibly cancer. He relies on statistical analyses from the AVERT study, defendant's Top Accounts study, and two of his own studies.

Defendant criticizes Butchart for his lack of knowledge of statistics. This argument is unpersuasive. Butchart is a highly qualified medical expert, and his conclusions are based in part on data that he personally generated. Statistical expertise is not needed to make his testimony about complication rates helpful for the jury.

Defendant next points out weaknesses in each of the studies relied upon by Butchart. For example, defendant criticizes Butchart's reliance on the Top Accounts study because it was not randomized. Again, these criticisms go to the weight of the testimony, rather than the admissibility. *See Bonner*, 259 F.3d at 929. Despite the weaknesses identified by defendant, the opinion offered by Butchart is certainly not based on "subjective speculation that masquerades as scientific knowledge." *Glastetter*, 252 F.3d at 989.

As such, the Court denies defendant's motion to preclude the testimony of Butchart.

ORDER

Based on the foregoing, and all the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant's Motion to Exclude Testimony of Plaintiffs' Pathology Expert Gregory J. Wilson [Docket No. 455] is **DENIED**.

2. Defendant's Motion to Exclude Testimony of Plaintiffs' Biomaterials Expert Kevin E. Healy [Docket No. 464] is **DENIED**.

3. Defendant's Motion for Order to Preclude Testimony of Plaintiffs' Expert Eric G. Butchart [Docket No. 468] is **DENIED**.

DATED: June 4, 2007
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge